(Refer to Tutorial Video, Mandatory Reporting & My Sejahtera via QR code on the outer box or this inset)

For Self -test Only

NEOTEST K+ COVID-19 ANTIGEN RAPID TEST (Oral Fluid)

NEOTEST K+

【Product Name】

NEOTEST K+ Covid 19 Antigen Rapid Test (Oral Fluid)

【Packaging specification】

1/25/50 Test(s) /kit

【Intended use】

This product is used to qualitatively detect the SARS-COV-2 Nucleocapsid (N) antigen in human saliva samples in vitro. No instrument required. It can be used for the screening of early infected patients and asymptomatic patients. The test can be performed for professional or self-testing use.

The negative result cannot rule out novel coronavirus infection, and it cannot be used alone as a basis for treatment and disease management decisions. The positive result of the antigen test can be used for early triage and rapid management of suspected infected people, but the positive result only indicates the presence of the novel coronavirus N-Protein (Nucleocapsid) in the sample and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by the novel coronavirus. It should be combined with nucleic acid testing, imaging and other diagnostic information, medical history, and contact history to determine the status of infection. Coronavirus belongs to the order Nidoviridae, and the coronavirus family is divided into three genera of α, β, and γ. α and β are only pathogenic to mammals, and γ mainly causes bird infections. COV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through fecal or oral routes.

【Testing principle】

The binding pad of this test strip was respectively covered with mouse anti-novel coronavirus monoclonal antibody 1 with colloidal gold as the color marker. The detection line (T) on the nitrocellulose cellulose membrane was covered with mouse anti-novel coronavirus monoclonal antibody 2 and the quality control line (C) was covered with goat anti-mouse IgG polyclonal antibody. When testing, when the sample to be tested contains the novel coronavirus, it combines with the colloidal gold-labeled novel coronavirus monoclonal antibody to form an immune complex, which is captured and enriched at the detection line (T) by the reagents fixed on the membrane. The colloidal gold-labeled antibody diffuses to the quality control line (C) area and is captured by the secondary antibody to form a purple-red band in the quality control area.

【Main components】

1. Test pad: Individually packaged in aluminum foil bags per test. The test pad consists of a sample pad, a gold-labeled pad labeled with a gold-labeled mouse anti-human SARS-COV-2 monoclonal antibody I, a nitrocellulose coated with a mouse anti-human SARS-COV-2 monoclonal antibody II, and a goat anti-mouse IgG antibody. It consists of plain film, absorbent paper, plastic backing and plastic template.
2. Medical waste bag
3. Instruction manual

【Storage conditions and validity】

1. Storage conditions: The original packaging should be stored in a dry place at 4~30°C, protected from light, and do not freeze.
2. Validity period: 18 months.
3. The reagent should be used as soon as possible within 1 hour after unpacking the aluminum foil bag; it is recommended to use it as soon as possible when the surrounding temperature is higher than 30°C or high humidity.

【Sample requirements】

1. This product is applicable to human saliva samples.
2. Samples that are heavily contaminated by oral food residues cannot be used for testing of this product. Saliva samples are not recommended to be used for testing of this product after a large amount of blood is contaminated.If the saliva samples are too viscous, the test results may vary significantly.

【Test method】

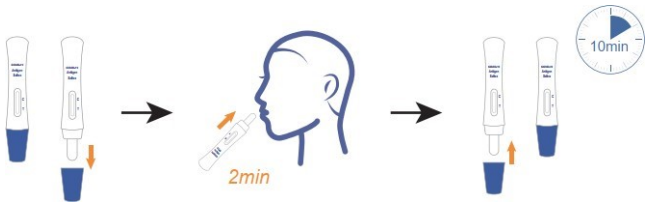
Please read the instruction manual carefully before testing. Please return all components to room temperature before the test. The test should be performed at room temperature.

Detection steps:

1. After the test pad returns to room temperature,open the aluminum foil bag of the test pad and take out the test pad.
2. Remove the blue cover of the test pad. Put all the water-absorbing parts of the sampler on both sides of the mouth and gently apply it, and finally press it under the tongue and soak it with saliva.You should salivate naturally until the red line onthe control area (C) line is visible.Wait patiently for about 2 minutes to remove it.Cover the blue cover of the test pad.
3. Place the test pad horizontally, read the displayed result within 10-15 minutes.The result is valid within 15 minutes.

Note:

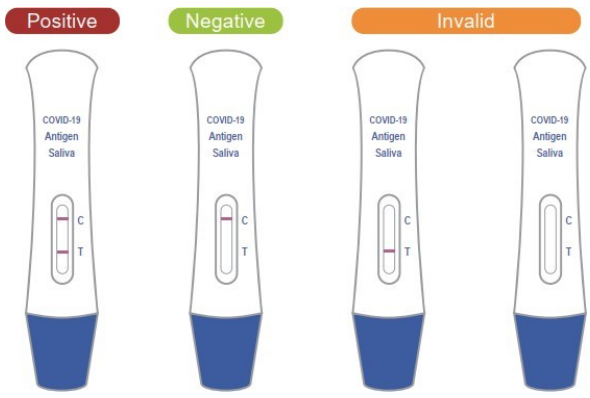
- Do not eat, drink or smoke for 2 hours before the test.
- Before the test, the user needs to cough deeply for more than 3 times, and use the saliva from the throat to test.
- The components after use should be treated in strict accordance with the medical waste, pay attention to protection.



【Interpretation of test results】

1. Positive: Two red bands, the detection area (T) and the control area (C) are bothred. A positive result means the presence of SARS-CoV-2 antigen. This means you are more likely to be infected with COVID-19. Immediately go into self-isolation according to local guidelines and immediately contact your general practitioner / doctor or local health department. PCR testing can confirm the results and please follow local guidelines for next steps.

   Report to MOH via MySejahtera App which can be accessed through the QR Code on the box or in this insert.
2. Negative: There is no red band in the detection area (T), and a red band appearsin the control area (C). A negative result means you do not have the antigen SARS-CoV-2 or Viral Load is too low to be detected by the test. You can still be infected with COVID-19 even if the test is negative. If you experience symptoms such as headache, migraine, fever, loss of sense of smell and taste, contact the nearest medical facility according to the guidelines provided by the local authorities. In addition, you can repeat the test with a new test kit after 1-2 days, because the coronavirus cannot be detected accurately in all phases of infection. Social distancing and hygiene rules must be followed even with a negative test result. Follow your local guidelines for activities such as traveling, attending events, etc.
3. Invalid: There is no red band in the control area (C), indicating that the test is invalid, and the test should be re-sampled.



【Limitations of test methods】

1. This product is only suitable for the detection of human saliva samples. It detects the virus content in the sample extract, regardless of whether the virus is infectious. Therefore, the test results of the same sample using this product may not be correlated with the virus culture results.
2. The test pad of this product needs to be restored to room temperature before use. Improper temperature may cause abnormal test result.
3. During the testing process, the test results did not match the clinical results due to in sufficient saliva collection samples or improper collection and specimen extraction operations.
4. During the use of this product, you need to strictly follow the operating steps of the manual. Improper operating steps and environment conditions may cause abnormal test results.
5. The positive test result of this product cannot distinguish between SARS-CoV and COVID-19.
6. A negative test result of this product cannot rule out the possibility of otherpathogens being positive.
7. Negative test results are recommended to be verified with nucleic acid detection reagents to avoid the risk of missed test.

【Performance characteristics】

Clinical performance
The clinical performance of Neotest K+ Covid 19 Antigen Rapid Test (Colloidal gold method) was determined by testing paired nasopharyngeal (NP) swab and saliva samples from 580 people suspected of COVID-19 infection. The results are as below:

2x2 table for calculation of coincidence rate				
		Comparator method		Total
		Positive	Negative	
NEOTEST K+ Covid 19 Antigen Rapid Test	Positive	199	2	201
	Negative	3	376	379
	Total	202	378	580
Positive coincidence rate (Clinical sensitivity)		98.51%（95.72% to 99.69%）		
Negative coincidence rate (Clinical specificity)		99.47%（98.10% to 99.94%）		
Overall percent agreement (Accuracy)		99.14%（ 98.00% to 99.72%		

1. Negative coincidence rate: using corporate negative reference products (N1-N20), the results are all negative, and the coincidence rate is 20/20.
2. Positive coincidence rate: tested with positive corporate reference products (P1-P8), the results are all positive, and the coincidence rate is 8/8.
3. Minimum detection limit: Use the company's minimum detection limit reference products S1, S2, S3, S4, S5, S6 for detection, S1-S4 should be positive, S5 can be positive or negative, and S6 is negative.
4. Repeatability: R1, R2 and R3 were tested 20 times respectively, the test results R1 should all be negative, the positive detection rate of R2 should be ≥95%, R3 should all be positive, and the color rendering is uniform without difference.
5. Differences between batches: Use 3 different batches of kits to detect the reproducible reference products R1, R2 and R3 respectively. R1 should all be negative, the positive detection rate of R2 should be ≥95%, and all R3 should be positive, and There is no obvious difference in color rendering.

【Precautions】

1. This kit is for scientific research only and is only used for in vitro testing. Please read these instructions carefully before experimenting and strictly follow the operating procedures in the instructions.
2. The collection, storage and testing of samples should be carried out in strict accordance with relevant guidelines.
3. After the inspection, the remaining samples are preserved and various waste treatments. The waste or remaining samples generated during the inspection process are recommended to refer to the above guidelines. First, diethylether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, chloroform and other lipid solvents are used to soak the virus for inactivating, and then the infectious agents are treated according to the above guidelines.

【References】

1. Lamarre A, Talbot PJ. Effect of pH and temperature on the infectivity of human coronavirus 229E. Canadian Journal of Microbiology. 1989;35(10):972-4.
2. Bucknall RA, King LM, Kapikian AZ, Chanock RM. Studies with human coronaviruses II.Some properties of strains 229E and OC43. Proceedings of the Society for Experimental Biology and Medicine. 1972;139(3):722-7.

【Manual approval and revision date】

November 18, 2021

【Production date and expiration date】

See label

LABEL INTRODUCE FOR USER

Abbreviation	Explanation	Abbreviation	Explanation
IVD	In vitro diagnostic medical device	LOT	Batch code
Σ	Contains sufficient for<n>tests		Date of manufacture
	Manufacturer		Use-by date
	Do not use if package damaged and consult instructions for use	30℃ 4℃	Temperature limit: 4~30℃
	Keep away from sunlight		Keep dry
	Consult instructions for use		Do not re-use
REF	Catalogue number		Biological risks

NEOPHARMA TECHNOLOGIES

Neopharma Technologies Sdn Bhd.
Unit 3.1, Level 3, Block A, Dataran PHB, Persiaran Golf,
Saujana Resort, Seksyen 2, 40150 Shah Alam, Malaysia.
Tel: +60(3)78426787
enquiries@neopharmatechnologies.com
https://neopharmatechnologies.com